Changing landscape of complex lead extractions: need for patient tailored use of armamentarium for very old leads

Arif Elvan¹

 $^1 \mathrm{Isala}$ Klinieken

September 24, 2021

Changing landscape of complex lead extractions: need for patient tailored use of armamentarium for very old leads

Arif Elvan, MD, PhD, FESC, FEHRA

Isala Heart Centre, Diagram Research, Zwolle, The Netherlands

Funding: None

Conflict of interest: None

The numbers of implanted cardiovascular implantable electronic devices (CIED) and leads increased tremendously in the past decades due to an expansion of indications and progressive ageing of the population. The increased demand for complex transvenous lead extractions (TLE) is mainly related to a higher relative incidence of CIED infections, malfunction of leads and the increased need for upgrading or revision of devices. Moreover, the landscape of lead extraction is changing in time with a relative increase in the proportion of old leads with a dwell time of [?]10 years (1, 2). The growing impact of these complex TLEs on the utilization of the health care system has driven dedicated invasive cardiac electrophysiologists and engineers to improve strategies and tools to enable operators to perform lead extractions in a safe, effective and patient-centered way, minimizing risks of morbidity and mortality. We all know that chronically implanted leads may develop extensive fibrous or calcified adhesions around the surrounding structures and require more complex extraction techniques. Of note, the ageing of leads is associated with decreased procedural and clinical success rates and increased risk of lead extraction related complications (1, 2, 3). Currently, the techniques and armamentarium used in the extraction of leads include traction, counter traction, locking stylets, telescoping sheaths, and powered rotational mechanical and laser sheaths.

In this issue of the Journal of Cardiovascular Electrophysiology, Issa (4) investigated success and complication rates of complex TLE of very old leads, defined as leads with a dwelling time of [?]20 years compared with younger leads. The indications for TLE were mainly related to pocket (58.9%) and systemic infections (33.9%), and in a minority of patients TLE was performed for other non-infectious indications. Although clinical success was very high in the current study (97.1%), this high clinical success implicates that small residual parts were regarded as a satisfactory result, while non-extracted remnants can be of clinical importance, especially in patients with lead endocarditis. Therefore, the complete procedural success constitutes an important metric rather than clinical success, particularly in patients with infectious TLE indications, in whom extraction of the whole system without any remnants should be the ultimate procedural endpoint.

Furthermore, in the study by Issa (4), patients were treated by a single experienced lead extraction specialist in a high-volume center. The results of this study cannot be extrapolated to less experienced operators or low volume centers. This study underlines the necessity of concentrating lead extractions to high-volume centers to provide the best care for these patients. Some single center series reported very low complication rates, which does not reflect potential complications that might be encountered during a complex lead extraction procedure, especially when performing extraction of very old leads with a dwelling time of [?]20 years. It seems reasonable to advocate that all lead extractions should be reserved to experienced centers with a thoracic surgeon standby during complex lead extraction procedures. It is, to my personal opinion, important to emphasize this issue instead of giving space for low volume centers to perform some of the expected "easy" lead extractions.

Moreover, in the study by Issa (4), the laser sheath was the primary extraction tool used in the majority of the [?]20 years old leads and mechanical sheaths or femoral snares were only used after failure of laser sheaths. Complete procedural success was lower in the group of patients with very old leads compared with leads with a dwelling time of less than 20 years (90.7% versus 98.5%). However, angiography of the subclavian vein was not a standard routine procedure in all patients. It seems reasonable to incorporate venous angiography as a standard procedure in the workup for TLE (5). Of note, the complexity of the TLE in the group with leads less than 20 years old was very heterogeneous. It is remarkable that 55% of the leads required complex extraction techniques, whereas 45% of these leads could be extracted with manual traction only in this group of patients with less than 20 years old leads, highlighting the nonbinary nature of the extent of adhesions of aging leads to surrounding structures. Despite advances in lead extraction techniques, extraction of older leads in a safe and effective way remains challenging. Issa (4) demonstrated that complex TLE can be performed successfully and safely by a skilled and experienced operator in a specialized center. The rate of major complications was 5.6% including 1 death. These results are in line with previous publications (5, 6, 7).

This latter study (4) underlines the importance of the use of combination of multiple extraction tools in enhancing procedural success rates. Especially in leads with a dwelling time of [?]20 years, there is an increased risk of extraction failure or incomplete success. Issa (4) primarily used laser sheaths while others used the powered mechanical sheath as the primary extraction tool. Several reports describing the results of case series were published on the success and complication rates of lead extractions with the use of mechanical sheaths (5, 6, 7). These studies described the results of case series. Moreover, Migliore et al (7) reported that complex lead extractions using the Evolution RL bidirectional rotational mechanical sheaths and ancillary tools in a systematic stepwise approach were effective and safe.

The use of dedicated extraction tools and techniques yielded reported major adverse event rates of 2-3% with a mortality of 1% in previous studies (3, 5, 6, 7). In some previous reports, only powered mechanical sheaths were used with comparable results (5, 6, 7). The currently available armamentarium for complex lead extractions including laser sheaths, powered mechanical rotational sheaths and femoral snares enables operators to tailor the procedure in order to enhance procedural and clinical success rates. However, there is a lack of direct comparative data regarding risks and benefits of laser sheath compared with powered mechanical sheaths and femoral snares.

Issa (4) performed analyses of retrospective data which should be regarded as exploratory and hypothesis generating. Nevertheless, this study provides data and conveys messages that are important to the clinical practice. The main finding is that transvenous extraction of leads with a dwelling time [?]20 years is associated with a considerable risk of major complications, even in the hands of an experienced operator and in the setting of a high-volume center. This study highlights the need for concentration of complex lead extractions to a selected number of highly specialized centers.

Although, direct comparison of the available strategies and techniques has not been performed yet, these studies need to be performed in the near future. Clinicians need guidance based on firm evidence regarding comparative efficacy or safety of bidirectional powered mechanical sheaths and laser sheaths and femoral snares.

There are no randomized trials comparing different extraction strategies. The current recommendations are based on outcome data derived from various case series.

Therefore, international collaboration, merging of databases and ultimately randomized trials are crucial to

gain more insight and to better delineate the incremental values of the available lead extraction tools and techniques.

The innovations in the field of complex TLE techniques and tools will continue. In the meantime, the extraction of chronically implanted leads remains a complex procedure associated with major complications including mortality, mandating concentration to specialized centers and standardized metrics for monitoring procedural and clinical outcomes.

References

- Priori SG, Blomström-Lundqvist C, Mazzanti A, Blom N, Borggrefe M, Camm J, et al; Task Force per il Trattamento dei Pazienti con Aritmie Ventricolari e la Prevenzionedella Morte Cardiaca Improvvisa della Società Europea di Cardiologia. [2015 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac Death. The Task Force for the Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death of the European Society of Cardiology]. G Ital Cardiol (Rome) 2016;17:108-70.
- 2. Brignole M, Auricchio A, Baron-Esquivias G, Bordachar P, Boriani G, Breithardt OA, et al; ESC Committee for Practice Guidelines (CPG)., Zamorano JL, Achenbach S, Baumgartner H, Bax JJ, Bueno H, Dean V, et al; Document Reviewers., Kirchhof P, Blomstrom-Lundqvist C, Badano LP, Aliyev F, Bänsch D, Baumgartner H, et al. 2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy: the Task Force on cardiac pacing and resynchronization therapy of the European Society of Cardiology (ESC). Developed in collaboration with the European Heart Rhythm Association (EHRA). Europace 2013;15:1070-118.
- 3. Kusumoto FM, Schoenfeld MH, Wilkoff BL, Berul CI, Birgersdotter-Green UM, Carrillo R, et al. 2017 HRS expert consensus statement on cardiovascular implantable electronic device lead management and extraction. Heart Rhythm 2017;14: e503-e551.
- 4. Issa ZF. Outcome of transvenous lead extraction of leads older than 20 years. Journal of Cardiovascular Electrophysiology. 2021 (current issue of the Journal).
- Bontempi L, Aboelhassan M, Cerini M, Salghetti F, Arabia G, Fabbricatore D, Maiolo V, Giacopelli D, Curnis A. Abandoned and fractured ICD lead with complete superior veins occlusion: Is transvenous lead extraction still possible? J Cardiovasc Electrophysiol. 2020 Nov;31(11):3042-3044. doi: 10.1111/jce.14752. Epub 2020 Sep 29. PMID: 32955129.
- 6. Delnoy PPHM, Witte OA, Adiyaman A, Ghani A, Smit JJJ, Ramdat Misier AR, Elvan A. Lead extractions: the Zwolle experience with the Evolution mechanical sheath. Europace 2016;18: 762-6.
- Migliore F, Testolina M, Sagone A, Carretta D, Agricola T, Rovaris G, Piazzi E, Facchin D, De Lazzari M, Zorzi A, Melillo F, Cataldi C, Marzi A, Bottio T, Tarzia V, Gerosa G, Iliceto S, Bertaglia E, Mazzone P. Multicenter experience with the Evolution RL mechanical sheath for lead extraction using a stepwise approach: Safety, effectiveness, and outcome. Pacing Clin Electrophysiol. 2019 Jul;42(7):989-997